

## November 19, 1998

9060 '98 NDV 24 P2 / 18

## Via Express Mail

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204

Silica Gel





Re: <u>Statements of Nutritional Support</u> Section 403(r)(6) Notification

## Ladies and Gentlemen:

In accordance with the requirements of Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Makes of KAL, Inc., having the address of 1500 Kearns Boulevard, Park City, Utah 84060, notifies the FDA that it has commenced the marketing of the following dietary supplement with the following statements of nutritional support:



<u>Product</u>	Relevant Dietary <u>Ingredients</u>	Statements of Nutritional Support
Silica Plus™	Horsetail Extract and Colloidal Hydrophilic	•Silica is an important trace minera which contributes to total body

•Silica is an important trace mineral which contributes to total body health. Most visible is its role in helping to maintain the health of the outside appearance of our body—our skin, hair, and nails. By acting as a glue-like substance, Silica may help hold together and strengthen connective and supportive tissues, which in turn add firmness and elasticity to skin, luster and body to hair and hardness to nails. Because skin levels of Silica decline with age, it is likely that other tissues may have higher Silica needs over a







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lifetime.

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- •On the inside, Silica may strengthen bones by facilitating the deposition of Calcium, Magnesium and Phosphorus within our bones. Without this important trace mineral, our bones and joints might soften, weakening our body's entire structural support system. Silica may also play a role in maintaining the health of the blood vessels.
- •The standardized amount of Silica Gel accentuates the nourishing properties of Horsetail.

I certify that the foregoing is complete and accurate, and that Makers of KAL, Inc. has substantiation that the statements are truthful and not misleading.

Very truly yours,

Makers of KAL, Inc.

By:

Christopher Neuberger, President

Specialty Category